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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/509,498	REIMANN ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed October 12, 2007 has been entered. Claims 1,4-6, and 9-11 have been amended. Claim 7 has been cancelled. Claim 12 has been newly added. Claims 1-6 and 8-12 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claims 10-11 under 37 CFR 1.75 (c);

b) The rejection of claims 1, 4 and 9 under 35 U.S.C. 112, second paragraph;

c) The rejection of claim 9 under 35 U.S.C. 101;

Response to Arguments

3. Applicant's arguments filed October 12, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition suitable for administration to a vertebrate host, which comprises:(a) a polynucleotide vaccine component comprising a polynucleotide encoding a vaccine Hepatitis B surface antigen, such that introduction of polynucleotide into said vertebrate host results in expression of a biologically effective amount of said antigen so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen vaccine component comprising a protein antigen selected from the group consisting of bovine serum albumin, hen egg lysozyme and Hepatitis B surface antigen; and (c) a mineral-based, negatively charged adjuvant, does not reasonably provide enablement for a vaccine composition suitable for administration to a vertebrate host, which comprises:(a) a polynucleotide vaccine component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said formulation into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response; (b) a protein antigen vaccine component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine protein antigens; and (c) a mineral-based, negatively charged adjuvant. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This is a scope of enablement rejection.

The specification shows that an antibody response was generated in mice, however it is well known that merely generating an immune response does not equate to providing protective immunity. The instant specification fails to provide any experiments that show that such vaccines would be effective in protecting a human or other vertebrate host against an undefined pathogen. There are still no immunological experiments provided to demonstrate that the claimed vaccines are capable of mounting an effective immune response. More importantly, there are no challenge experiments to demonstrate that a vertebrate host immunized with the claimed vaccine composition would be protected from any infection. There are no protocols provided which demonstrate which composition would be effective in immunization, nor are their protocols detailing the amount of vaccine composition needed to mount a sufficient immune response. There is no teaching as to what the most effective route of administration for the claimed vaccines. There is merely a general outline of vaccines that do not apply directly to the instant invention. The ability to reasonably predict the capacity of a single immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic.

Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or

microbial pathogen that itself can elicit the production of protective antibodies" (page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Factors to be considered in determining whether undue experimentation is required are set forth in *In re Wands* 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. i .132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting polynucleotides and protein antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or

use a polynucleotide vaccine component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said formulation into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen vaccine component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine protein antigens; and (c) a mineral-based, negatively charged adjuvant in manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Since the nucleotide sequence determines its structural and functional properties, predictability of which changes can be tolerated and still retain similar activity requires a knowledge with regard to the nucleotides sequence, and the detailed knowledge of the ways in which the encoded protein's structure relates to function. However, the problem of the prediction of protein's structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein with respect thereto is extremely complex and outside of the realm of routine experimentation. It is not routine in the art to screen multiple polynucleotides that encode at for a vaccine antigen, and protein antigen compositions with a reasonable expectation of success. Thus the art indicates that it would require undue experimentation to formulate and use a successful vaccine composition without the prior demonstration of vaccine efficacy.

Response to Arguments

5. Applicants argue that the specification at page 9 provides guidance , however the specification teaches the mixing of a plasmid Hepatitis B surface antigen (HBsAg) DNA, a protein antigen encoding the same, aluminum phosphate and either bovine serum albumin (BSA) or hen egg lysozyme (HEL); see page 9 of the instant specification. The specification has failed to provide a structure for all of the polynucleotide vaccine components and protein antigen vaccine components encompassed by the claimed invention. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and protein antigens broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative vaccine compositions, contrary to applicants arguments.

Applicants point out that they are there own lexicographer, however page 5, lines 24-26 state that the vaccine protein antigen induces specific and protective immunity towards the infection caused by the organism that vaccine protein. It is noted that the claims and specification fail to disclose the specific type of vaccine components that should be administered. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to an infection or disease induction. The vaccine art is highly unpredictable and the instant specification fails to provide any information that the recited vaccine would provide any immunity to a vertebrate host against any type of infection.

Applicant has not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. Without such guidance, the vaccine composition's activity is unpredictable and the experimentation left those skilled in the art is unnecessarily and improperly, extensive and undue.

This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing any infection or disease. Without this, demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced. The specification fails to teach the identity a vaccine composition with the claimed characteristics. Furthermore, the specification fails to adequately disclose a description of the claimed vaccines, thus a skilled artisan would be required to de novo locate, identify and characterize the claimed vaccines. Accordingly, this would require undue experimentation given the fact that the specification is completely lacking in teachings. Thus, the art indicates that it would require undue experimentation to formulate and use a successful vaccine composition without the prior demonstration of vaccine efficacy. Therefore, applicants arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 5 recites alternative limitations for the group of vaccine protein antigens which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicants amendments have not corrected this, therefore it is suggested that amending the claim to recite the appropriate language is suggested.

b) The preamble of claim 9 is drawn to a method of using a mineral-based, negatively charged adjuvant as a component in a combined DNA/protein-based vaccine composition, however the recited steps within the method comprise of preincubating or subsequent mixing of the adjuvant. There is no correlation step which correlates the use of the adjuvant to the body of the claim. Therefore, the goal of the preamble is not commensurate with the steps of the method that are drawn to using the adjuvant. It is unclear what use applicant is intending to encompass.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dalemans et al., (WO 99/30733).

The claims are drawn to a vaccine composition suitable for administration to a vertebrate host, which comprises: (a) a polynucleotide vaccine component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said polynucleotide vaccine component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen vaccine component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine protein antigens; and (c) a mineral-based, negatively charged adjuvant wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen vaccine component prior to formulating with said polynucleotide vaccine component. The dependant claims are drawn to specific

adjuvants, model protein antigens, and vaccine protein antigens. The claims are also drawn to a kit comprising the vaccine composition and a method of using the adjuvant as a component in a combined DNA/protein based vaccine composition and a method for preparing the vaccine component.

Dalemans et al., teach administration of combination DNA vaccines to mammals such as man (page 3, lines 28-30). Dalemans et al., teach DNA vaccines by admixing two different compounds wherein the first compound comprises a polynucleotide (nucleic acid) such as DNA or RNA which-encodes a selected polypeptide that can stimulate protective immunity and the second compound comprises a polypeptide, which preferably is the same polypeptide (or substantially the same, i.e., having the same immunodominant epitope(s) encoded by the nucleic acid (page 5-6, lines 29-2). When nucleic acid such as DNA encoding the gene of interest is admixed with the corresponding polypeptide is administered to a mammal, a synergistic effect is observed wherein not only is the DNA vaccine capable of inducing an immune response in the presence of protein (polypeptide), but the presence of such protein (polypeptide) has been found to actually enhance the efficacy of the DNA vaccine (page 6, lines 6-11). Thus, one aspect of the present invention is a composition comprising a polynucleotide and polypeptide for enhancing an immune response wherein the polypeptide is adjuvanted (page 6, lines 11-14).

Dalemans et al., teach prior mixing of the polypeptide or protein antigen with the adjuvant. The polynucleotide comprises DNA or RNA polynucleotide

sequences coding for polypeptides that have useful therapeutic application, e.g., prophylactic or therapeutic vaccines (page 7, lines 14-16). Both expressible DNA and RNA can-be delivered to cells to form therein a polypeptide translation product wherein the encoded antigens are associated with infectious diseases caused by, for instance, all forms of Hepatitis and polio, (page 5, lines 17-22). The protein antigen can be a polypeptide that also has a useful therapeutic application such as a prophylactic or therapeutic vaccine (page 6, lines 20-21). The vaccine composition is not limited to a particular polypeptide and can have the same immunodominant epitopes encoded by the nucleic acid (page 6, lines 21-22). Dalemans et al., that the polypeptide or protein antigen component can comprise an antigen a surface protein or an antigen derived from inactivated polio virus. Dalemans et al., teach the administration of a polynucleotide/polypeptide composition, should enhance the induction of immunity because the administration of one compound also both components to act during the same ongoing immune response (page 7, lines 25-29 and page 8, line 10). The polynucleotide + polypeptide mixture (complex), when adjuvanted, preferably adjuvanted with suitable adjuvants that include an aluminum salt such as aluminum hydroxide (alum), aluminum phosphate, but also can be a salt of calcium (page 18-25). Therefore, Dalemans et al., teach a mineral-based, negatively charged adjuvant that is an aluminum or calcium salt, such as aluminum hydroxide and aluminum phosphate.

Dalemans et al., teach a method of using the adjuvant as a component in a combined DNA/protein vaccine composition. Dalemans et al., teach that the vaccine formulation includes an adjuvant that encodes CpG sequences, wherein such CpG sequences, or motifs, are known in the art (page 10, lines 4-6). The art teaches that palindromic CpG sequences have immunostimulatory activities and are instrumental in aiding DNA vaccine by providing an activation signal to antigen presenting cell. The instant specification at page 5, lines 12-15 define model protein antigens as a protein which is not derived from an infectious microorganism which may cause one or more diseases with the aim of eliciting a protective immune response towards the model protein itself. The CpG sequence meets the limitation of being a model protein antigen since CpG is not derived from an infectious microorganism which may cause one or more diseases and the protein does not elicit a protective immune response towards. CpG. Dalemans et al., teach the inclusion of a model protein. Dalemans et al., teach that the composition is packaged in a per unit dosage or unit dosage ampoules or multidose containers, in which the polynucleotides and polypeptides are packaged prior to use enclosing an amount of polynucleotide and polypeptide or solution containing a polynucleotide and polypeptide suitable for a pharmaceutically effective dosing (page 11, lines 2-30). Therefore teach a unit dose form for administration to a vertebrate recipient. Dalemans et al., also teach a kit comprising the vaccine composition in unit dosage form and a method of using the adjuvant as a component in the combined DNA/protein vaccine composition.

Accordingly, Dalemans et al., teach the instantly claimed inventions.

Response to Arguments

8. Applicants argue that Dalemans et al., provides a general list of adjuvants without specifying a preference for mineral-based negatively charged adjuvants, therefore the rejection over Dalemans et al. should be withdrawn.

However, something which is old does not become patentable upon the assertion or discovery of a new property. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Therefore, applicants' arguments about the list of Dalemans adjuvants within the composition are not persuasive.

Contrary to applicants' argument, the Dalemans et al., teach the instant claims. The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277

(CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Therefore applicant's argument is not persuasive especially when considering that Dalemans et al., teach every single component of the vaccine composition, therefore the rejection is maintained.

Applicants' urge that Dalemans et al., do not provide any order of mixing the components, therefore the rejection is not anticipated. In response to applicants' argument that the references fail to show certain features of applicants' invention, it is noted that the features upon which applicant relies (i.e., an order for mixing the components) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the claims are drawn to a vaccine composition, thus the order of mixing the components does not change the components of the composition which Dalemans et al., teach.

Applicants assert that the product of Dalemans et al., differs from the product according to the present invention. In response to applicant's argument, the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In this case, the prior art structure has the same components, (a) a polynucleotide vaccine component comprising at least one polynucleotide

encoding at least one antigen, such that introduction of said polynucleotide vaccine component into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;(b) a protein antigen vaccine component comprising at least one protein antigen selected from the group consisting of model protein antigens and vaccine protein antigens; and (c) a mineral-based, negatively charged adjuvant wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen vaccine component prior to formulating with said polynucleotide vaccine component, thus the compositions of Dalemans et al, meets the claim limitations.

It is noted that the interpretative "wherein" clause as recited in the claims (wherein said mineral-based negatively charged adjuvant is preincubated or subsequently mixed with said at least one protein antigen vaccine component prior to formulating with said polynucleotide vaccine component as recited in claims 1 and 9) does not recite ant additional active method steps but simply states a characterization or conclusion of the results of those steps. Therefore the "wherein" clause is not considered to further limit the method defined by claim 9 and has not been given weight in construing the claims. See *Texas Instruments, Inc. v. Int'l Trade Comm'n*, 988 F.2d 1165, 26 USPQ2d 1018 (Fed. Cir. 1993)("A whereby clauses that merely states the results of the limitation in the claim adds nothing to the patentability or substance of the claim".) See also *Minton v. Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67

USPQ2d 1614, 1620 (Fed.Cir. 2003)) that a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" Therefore the rejection is maintained because the wherein clause is not considered to further limit the claims, does not recite ant additional active method steps and thereby has not been given weight in construing the claims and applicants arguments are not persuasive.

New Grounds of Objection

Claim Objections

9. Claim 1 is objected to because of the following informalities: Claim 1 recites "polynucletide" instead of "polynucleotide". Appropriate correction is required.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 12, 2007

MARK NAVARRO
PRIMARY EXAMINER